UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. HANMI USA, INC., et al. Defendants.	Civil Action No. 11-760 (JAP) **OPINION**

PISANO, District Judge.

In this Hatch-Waxman patent infringement action brought by Plaintiffs AstraZeneca AB, Aktiebolaget Hässle, AstraZeneca LP, KBI Inc. and KBI-E Inc. (collectively, "AstraZeneca" or "Plaintiffs") against defendants Hanmi, Inc., Hanmi Pharmaceutical Co., Ltd., Hanmi Fine Chemical Co., Ltd. and Hanmi Holdings Co., Ltd. (collectively, "Hanmi" or "Defendants"), Hanmi originally filed five motions seeking summary judgment. Two of the motions, those designated by the parties as Motion No. 1 and Motion No. 5, were previously decided by the Court. *See* Opinion and Order, D.I. 226, 227. This Opinion addresses the remaining three, specifically, those motions designated by the parties as Motion No. 2, Motion No. 3 and Motion No. 4. The Court heard oral argument on Motion Nos. 2 and 4, and it decides the remaining motion without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons below, the Court denies Hanmi's motions.

I. BACKGROUND

A background summary is set forth in the Court's earlier Opinion and, therefore, need not be repeated here. *See* Opinion at D.I. 226. Facts relevant to each of the instant motions are set forth below.

II. SUMMARY JUDGMENT MOTIONS

A. Summary Judgment Standard

A court shall grant summary judgment under Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The substantive law identifies which facts are critical or "material." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. *Healy v. N.Y. Life Ins. Co.*, 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the moving party makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. *Id.* at 324. The non-moving party must then offer admissible evidence that establishes a genuine issue of material fact, *id.*, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but

need determine only whether a genuine issue necessitates a trial. *Anderson*, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. *Big Apple BMW v. BMW of North America*, 974 F.2d 1358, 1363 (3d Cir. 1992).

B. Motion No. 2 – Invalidity Of U.S. Patent No. 5,877,192 – Claims 12, 19, 21, and 22

The '192 patent describes and claims a method for treating gastric acid related diseases with esomeprazole and a method for the production of an esomeprazole-containing medicament for treating gastric acid related diseases. The claimed inventions are based on the discovery that esomeprazole has certain improved properties, and provides certain biological benefits, as compared to the prior art racematic compound omeprazole. The '192 patent states that it issued from an application that was a continuation-in-part of U.S. Patent Application No. 08/376,512 filed January 23, 1995, later issuing as U.S. Patent No. 5,714, 504, which was a continuation-in-part of U.S. Patent Application No. 08/256,174 filed June 28, 1994, later issuing as United States Patent No. 5,693,818. As alleged by AstraZeneca, the "family tree" of the '192 patent can be summarized as follows:

- Swedish Priority Application SE 9301830-7 (filed May 28, 1993) →
- Patent Cooperation Treaty application ("PCT application") designated PCT/SE/00509, filed May 27, 1994 (" '509 application"), which published as WO '988 on December 8, 1994 →
- United States Patent Application (a national stage application under 35 U.S.C. § 371) No. 256,174 (the '174 application) filed June 28, 1994, later issuing as United States Patent No. 5,693,818 (the "'818 patent") →

- United States Patent Application No. 376,512 (the "'512 application") filed January 23, 1995, later issuing as the (the "'504 patent") →
- United States Patent Application No. 833,962 (the "'962 application") filed April 11, 1997, later issuing as the '192 patent.

Thus, according to AstraZeneca, the '192 patent claims priority to the applications leading to the '504 patent and the '818 patent.

Hanmi seeks summary judgment that claims 12, 19 and 21-22 (to the extent dependent on claims 12 and 19) of the '192 patent are anticipated and therefore invalid. Specifically, Hanmi alleges that claims 12, 19 and 21-22 are anticipated and invalid under 35 U.S.C. § 102(b) because each limitation of those claims is allegedly found in WO 94/27988, published December 8, 1994 ("WO '988"). Hanmi contends that the '192 patent is not entitled to claim the benefit of a filing date earlier than its April 1997 filing date, and, therefore, the WO '988 reference is a prior art reference that anticipates the disputed claims. AstraZeneca disputes that the WO '988 is a prior art reference.

1. Legal Standards

a. Anticipation

A patent is invalid if "the invention was patented or described in a printed publication in this or a foreign country … more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b). If "each and every limitation is found either expressly or inherently in a single prior art reference," then a claim is invalid under § 102 for anticipation. *Sanofi-Synthelabo v. Apotex*, Inc., 470 F.3d 1368, 1375 (Fed. Cir. 2006) (quoting *Celeritas Techs. Ltd. v. Rockwell Int'l Corp.*, 150 F.3d 1354, 1361 (Fed. Cir. 1998)). Anticipation is a question of fact that must be established by clear and convincing evidence.

Sanofi–Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1082 (Fed. Cir. 2008). Although a fact question, summary judgment of anticipation may be appropriate if there is no genuine dispute of any material fact. *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010).

b. Priority

Section 120 of Title 39 of the United States Code governs entitlement of a patent application to an earlier filing date and provides that an application for a patent may "have the same effect, as to such invention, as though filed on the date of the prior application" if certain requirements are met.[1] The Federal Circuit has summarized these requirements as follows:

> A patent is entitled to the priority date of an earlier filed application if (1) the written description of the earlier filed application discloses the invention claimed in the later filed application sufficient to satisfy the requirements of § 112; (2) the applications have at least one common inventor; (3) the later application is filed before the issuance or abandonment of the earlier filed application; and (4) the later application contains a reference to the earlier filed application.

In re NTP, Inc., 654 F.3d 1268, 1277 (Fed. Cir. 2011). Further, "if the later filed application claims priority through the heredity of a chain of applications, each application in the chain must satisfy § 112." *Id.* "[I]f any application in the priority chain fails to make the requisite disclosure of subject matter, the later-filed application is not entitled to the benefit of the filing date of applications preceding the break in the priority chain." *Hollmer v. Harari*, 681 F.3d 1351, 1355 (Fed. Cir. 2012)

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[1]This section reads in the relevant part as follows:

> [a]n application for patent for an invention disclosed in the manner provided by section 112(a) (other than the requirement to disclose the best mode) in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application[.]

35 U.S.C. § 120.

2. Analysis

As noted earlier, Hanmi contends that claims 12, 19, 21 and 22 of the '192 patent are anticipated by WO '988 because the WO '988 reference is prior art against the '192 patent claims and each and every limitation in these claims is allegedly disclosed in WO '988. Hanmi's position that the WO '988 reference is a prior art reference is based upon two independent grounds. First, Hanmi alleges that the WO '988 reference is admitted in the '192 patent to be a prior art reference. Second, Hanmi argues that the '192 patent is not entitled to priority to any earlier application and, therefore, the WO '988 reference is a statutory prior art reference under § 102(b) because it was published more than one year before the effective filing dates of the claims at issue.

In response, AstraZeneca does not contest the substantive basis of Hanmi's anticipation argument, but instead challenges the availability of the WO '988 reference as prior art. AstraZeneca first contends, contrary to Hanmi's assertions, that the WO '988 reference is not "admitted" prior art. AstraZeneca further argues that the '192 patent is entitled to priority to at least the '174 application, which pre-dates the WO '988 reference. The Court addresses each argument in turn below.

As relevant to Hanmi's first argument, the "Background of the Invention" section of the '192 patent acknowledges that the "[d]ifferent salts of the single enantiomers of omeprazole" were described in the WO '988 reference. '192 patent, col. 1, lines 63-64. Hanmi contends that this statement "set the stage" for the invention described in the following sections and that, when read in context, the '192 patent characterizes the WO '988 reference as prior art. Hanmi argues that such statements are binding upon AstraZeneca for the purposes of whether the WO '988 reference is prior art against the '192 claims. Additionally, Hanmi notes that the applicant

submitted the WO '988 reference as part of an Information Disclosure Statement ("IDS") with the Patent Office during prosecution of the '192 patent in which the applicant described WO '988 as a reference. According to Hanmi this is a confirmation by AstraZeneca of the prior art status of WO '988 (although Hanmi is clear that it is not arguing that the filing of the document in the IDS constituted an admission that it is prior art).

AstraZeneca responds to Hanmi's assertions by pointing out that "[o]ne's own work may not be considered prior art in the absence of a statutory basis." *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003) ("[A] patentee should not be 'punished' for being as inclusive as possible and referencing his own work in an [Information Disclosure Statement]."); *Reading & Bates Construction Co. v. Baker Energy Resources Corp.*, 748 F.2d 645, 650 (Fed. Cir. 1984) ([T]here is an important distinction between the situation where the inventor improves upon his own invention and the situation where he improves upon the invention of another. In the former situation, where the inventor continues to improve upon his own work product, his foundational work product should not, without a statutory basis, be treated as prior art solely because he admits knowledge of his own work."). As these cases make clear, patents issued to the same inventive entity are not prior art by admission. *Riverwood*, 324 F.3d at 1355. One of the two inventors listed in the '192 patent is Per Lindberg. One of the two Inventor/Applicants listed in the WO '988 reference is Per Lindberg. As such, and in light of the early stage of the case and the limited record before it on the question, the Court finds that Hanmi has not shown that entry of summary judgment in its favor based on the issue of "admitted" prior art is appropriate.

Turning to Hanmi's second argument, the Court finds that issues of material fact exist that preclude summary judgment. Hanmi argues that the WO '988 reference is a statutory prior

art reference under § 102(b) because the '192 patent is not entitled to the benefit of the filing dates of the earlier applications. As relevant to the instant motion, the '192 patent claims priority back to the mid-1994 filing date of the '174 application, prior to the December 1994 publication of WO '988. As noted earlier, under 35 U.S.C. § 120, the '192 patent is entitled to the benefit of the filing date of an earlier application if four basic requirement are met.

> First, the invention described in the new application must be disclosed [in the manner provided by 35 U.S.C. § 112] in an application previously filed in the United States. Second, the application must be filed by an inventor or inventors named in the previously filed application. Third, the application must be co-pending with the earlier application, or filed before the patenting or abandonment of or termination of proceedings on the first application. Fourth, the application must contain or be amended to contain a specific reference to the earlier filed application.

Encyclopaedia Britannica, Inc. v. Alpine Electronics of America, Inc., 609 F.3d 1345, 1350 (Fed. Cir. 2010) (internal citations, quotations omitted). "The plain and unambiguous meaning of [§] 120 is that any application fulfilling the requirements therein shall have the same effect as if filed on the date of the application upon which it claims priority." *Transco Prods., Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 556 (Fed. Cir. 1994) (internal quotation omitted). In the instant case, the first factor -- continuity of disclosure -- is the only factor disputed, and, therefore, the sole issue for resolution of Hanmi's motion is whether this requirement has been met. *See* Def. Brf. at 10.

"In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997). Hanmi's argument regarding the alleged lack of continuity centers on its contention that the '512 application does not disclose the subject matter of the claims at issue as required by § 112. Specifically, Hanmi claims that this immediate parent

application does not disclose the neutral or free base form of esomeprozole in a medicament for the treatment of gastric acid related diseases, which is an element in each of the claims at issue on this motion. Thus, according to Hanmi, the alleged break in the priority chain negates entitlement to any earlier filing date.

In response to Hanmi's motion, AstraZeneca has submitted the declaration of Dr. Davies who concludes that the compounds described in the '504 patent "quite clearly include at least the optically pure (-)-enantiomer of omeprazole in both neutral and salt forms." Davies Decl. ¶ 60; *see also* ¶¶ 59-62. Dr. Davies opines that to a person of ordinary skill in the art, the neutral form of esomeprazole and its use as a medicament for the treatment of gastric acid related diseases is described in the '504 patent. *Id.* ¶ 63. He reaches a similar conclusion regarding the '818 patent. *Id.* ¶ 68. As such, the Court finds that AstraZeneca has shown there are disputed issues of material fact that include whether using the neutral form of esomeprazole in a medicament for the treatment of gastric acid related diseases is disclosed in the earlier applications as required by § 120. Consequently, such disputed issues of material fact preclude the summary judgment that Hanmi seeks by way of this motion. The Court denies Hanmi's motion No. 2.

C. Motion No. 3 - Invalidity Of U.S. Patent No. 5,714,504 – Claims 1, 2, 4, 6, and 7

Hanmi moves for summary judgment of invalidity of the '504 patent, claims 1, 2, 4, 6, and 7. Hanmi's motion centers on its contention that the claim term "solid state" is indefinite, and, therefore, the asserted claims fail. Hanmi also argues that the patent is invalid because the "solid state" salts of the asserted claims are neither adequately described or enabled.

1. Legal Standards

a. Indefiniteness

To be sufficiently definite, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. The boundaries of the claim must be discernible to one skilled in the art based on the language of the claim, the specification, and the prosecution history, as well as that person's knowledge of the relevant field of art. *See Halliburton Energy Servs., Inc. v. M–ILLC*, 514 F.3d 1244, 1249–51 (Fed. Cir.2 008). Claims that are "not amenable to construction" or "insolubly ambiguous" are indefinite. *Datamize LLC v. Plumtree Software*, Inc., 417 F.3d 1342, 1347 (Fed. Cir. 2005). The Federal Circuit has noted that "because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet an exacting standard." *Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 783 (Fed. Cir. 2010) (quotations omitted). "[A] claim is indefinite only if the 'claim is insolubly ambiguous, and no narrowing construction can properly be adopted.' " *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1338–39 (Fed. Cir. 2003) (*quoting Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).). However, "[i]f the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon*, 265 F.3d at 1375.

b. Written Description and Enablement

One of the statutory conditions for patentability under the Patent Act is adequate disclosure of the invention. As set forth in Section 112 of Title 35,

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

35 U.S.C. § 112. The Federal Circuit has interpreted § 112 as imposing a number of separate disclosure requirements, two of which are relevant here. The first is known as the written description requirement, found in the first sentence of Section 112, which requires that the specification contain an adequate "written description of the invention." 35 U.S.C. § 112; *see also Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-54 (Fed. Cir. 2010) (en banc) ("[A] separate requirement to describe one's invention is basic to patent law. Every patent must describe an invention. It is part of the *quid pro quo* of a patent; one describes an invention, and, if the law's other requirements are met, one obtains a patent. The specification must then, of course, describe how to make and use the invention (*i.e.*, enable it), but that is a different task.").

"[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353-54 (Fed.Cir.2010) (en banc). It "serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based and to demonstrate that the patentee was in possession of the invention that is claimed." *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

As stated by the Federal Circuit, "[t]he test for sufficiency of a written description is whether the disclosure clearly allow[s] persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." *Crown Packaging Technology, Inc. v. Ball Metal*

Beverage Container Corp., 635 F.3d 1373, 1380 (Fed. Cir. 2011) (internal quotations omitted, alterations in original). The "hallmark of written description is disclosure," and a court examining the sufficiency of a written description must make "an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. To pass muster under that inquiry, "[t]he disclosure must reasonably convey[ ] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Crown*, 635 F.3d at 1380 (internal quotations omitted, alteration in original). Said another way, "the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed." *Ariad*, 598 F.3d at 1351.

"[D]etermining whether a patent complies with the written description requirement will necessarily vary depending on the context." *Id.* The requirement "must be applied in the context of the particular invention and the state of the knowledge." *Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005). The inquiry into the written description requirement is a question of fact, however, it is "amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353, 1361 (Fed. Cir. 2011) (quoting *PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)). A party challenging a patent based upon the written description requirement must provide clear and convincing evidence that persons skilled in the art would not recognize in the disclosure a description of the claimed invention. *Centocor Ortho Biotech, Inc. v. Abbott Laboratories*, 636 F.3d 1341, 1347 (Fed. Cir. 2011) (presumption of validity overcome only by clear and convincing evidence).

Separate from the written description requirement is the "enablement" requirement codified in § 112. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (Fed. Cir. 2010) (quoting *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997). "Enablement is not precluded where a 'reasonable' amount of routine experimentation is required to practice a claimed invention, however, such experimentation must not be 'undue.'" *Id.* In *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988), the Federal Circuit set forth the following factors that a court may consider when determining if a disclosure requires undue experimentation:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

858 F.2d at 737. A court need not consider all of the *Wands* factors in its analysis, but rather, a court is only required to consider those factors relevant to the facts of the case. *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991).

Importantly, to fulfill the enablement requirement, the full scope of each claim must be enabled. *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008).

> Enabling the full scope of each claim is part of the *quid pro quo* of the patent bargain. A patentee who chooses broad claim language must make sure the broad claims are fully enabled. The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims.

Id. It is not sufficient for the specification to provide merely "a starting point, a direction for further research"; it must provide "reasonable detail" sufficient to enable a person of ordinary

skill in the art to make or use the invention. *Automotive Technologies Intern., Inc. v. BMW of North America, Inc.*, 501 F.3d 1274, 1284 (Fed. Cir. 2007). Whether the enablement requirement has been satisfied is a question of law based upon underlying facts, and is determined as of the patent's effective filing date. *Sitrick*, 516 F.3d at 999.

2. Analysis

AstraZeneca argues that Hanmi's motion should be denied for a number of reasons. In particular, it points to this Court's earlier ruling in a related case that the term "solid state" as used in the claims of the '504 patent has a plain and ordinary meaning to one that is skilled in the art. *See AztraZeneca AB v. Dr. Reddy's Laboratories, Ltd.*, 2010 WL 1981790, *9 (D.N.J. 2010). This Court in *Dr. Reddy's* held with regard to the term "solid state" that "no construction of this term is necessary [and] that its ordinary and customary meaning would be clear to one skilled in the art." *Id.* However, Hanmi's motion relies largely on its contentions that the term has no recognized meaning in describing pharmaceutical substances, and it argues that the term is not defined or described in the relevant patent application.

According to AstraZeneca's expert Professor Davies, whose declaration was submitted in response to this motion, one of ordinary skill in the art would have at the relevant time understood the term "solid state" to have an art-accepted meaning. Specifically, Dr. Davies states that the plain meaning of "solid state" is solid material in any form. Davies Decl. ¶ 80, 83. Hanmi contends that this Court rejected such a construction in its *Dr. Reddy's* decision, and Hanmi relies a great deal on this assumption. *See* Reply at 7 ("In reliance on the Court's prior rejection of solid state as meaning 'solid form rather than liquid, such as syrup or oil" … Hanmi asserted [the instant defenses]."). However, a careful reading of the Court's decision shows that, in fact, the Court did not determine (as Hanmi asserts) that "solid form" cannot

mean, for example, "solid material." Rather, the Court simply found it unnecessary in *Dr. Reddy's* to adopt either parties' proposed construction.[2] While Hanmi makes much of the Court's earlier purported "rejection," Hanmi misinterprets it. Given the *Dr. Reddy's* parties' arguments, their similar proposed constructions, and the nature of the claim term, the issue before the Court in *Dr. Reddy's* with respect to the term "solid state" was more about the extent to which claim construction was necessary than which (if either) of the parties' proposed constructions should be adopted. *See National Oilwell Varco, L.P. v. Auto–Dril, Inc.*, No. 09-85, 2011 WL 3648532, at *6 (E.D. Tex. Aug.16, 2011) (noting that "[w]hile it is a district court's duty is to construe the claims, part of this duty is to determine the extent [to which] construction is even necessary.). The Court ultimately determined in *Dr. Reddy's* that that no construction was necessary and the plain meaning should control in that case. *Id.* Contrary to Hanmi's assertions, such a finding does not necessarily constitute a "rejection" of any particular construction, nor does it foreclose the possibility that the Court may need to adopt an express construction of the term in this case.

In light of the arguments raised in Hanmi's motion and the parties' disagreement over whether the claim term "solid state" has an ordinary and customary meaning, it has become apparent that adoption of a construction for "solid state" is necessary in this case. "When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve that dispute." *O2 Micro International Ltd. v. Beyond Innovation Technology Co.*,

[2] Indeed, Hanmi itself notes that the parties in Dr. Reddy's "proposed essentially the same construction." Reply at 7. A court is not required to construe a claim term when there is not a genuine dispute as to its meaning. *See O2 Micro Intern. Ltd. v. Beyond Innovation Tech. Co.*, Ltd.. 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims"); *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy.").

521 F.3d 1351, 1360 (Fed. Cir. 2008). The Court finds that AstraZeneca's proposed construction, *i.e.*, that "solid state" means "solid material," is most consistent with the plain and ordinary meaning of the term, as well as with the Court's earlier conclusion that the meaning of the term is clear to one skilled in the art. The Court also credits the opinion of Dr. Davies, who opined that "a person having ordinary skill in the art would have found the "solid state" alkaline salts to be understandable with a clear and ordinary meaning of solid material." Davies Decl. ¶ 93. Consequently, the Court shall construe "solid state" consistent with AstraZeneca's proposed construction to mean "solid material." The Court rejects Hanmi's contention that the term "solid state" is indefinite.

Having rejected Hanmi's argument that a person of skill in the art would have found the term "solid state" to be unclear, the Court further finds that Hanmi has also failed to establish by clear and convincing evidence that claims 1, 2, 4, 6 and 7 of the '504 patent do not satisfy the written description requirement of Section 112. The '504 patent discloses how to make alkaline salts of (-)-omeprazole that in forms that a person of ordinary skill would recognize as solid state -- crystalline form, amorphous form, powders, tablets. *See* Davies Decl. ¶ 83. The specification of the '504 patent describes the alkaline salt products of (-)-omeprazole as "crystalline"). '504 patent, col. 1, lines 56-58; col. 3, lines 35-37, 40-41. Multiple examples detail the preparation of alkaline salts of (-)-omeprazole in crystalline form and as powder. In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue." *Yingbin–Nature (Guangdong) Wood Industry Co., Ltd. v. International Trade Com'n*, 535 F.3d 1322, 1334 (Fed. Cir. 2008) (quoting *Purdue Pharma L.P.v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000)).

Finally, the Court agrees with AstraZeneca that, with respect to enablement, issues of material fact preclude summary judgment. Hanmi's motion with respect to enablement depends largely upon its assertion that "solid state" is not capable of being defined, a proposition that the Court has rejected. Having examined the relevant *Wands* factors in light of the claim construction set forth above, the Court finds that fact issues preclude summary judgment and denies Hanmi's motion.

D. Motion No. 4 – Invalidity Of U.S. Patent No. 5,714,504 – Claims 1, 2, 4, 6 and 7

Claims 1, 2, 4, 6 and 7 are directed to "pharmaceutical formulation[s]" comprising "a pure solid state alkaline salt" of esomeprazole and methods of use thereof for "inhibiting gastric acid secretion" and treatment of gastrointestinal inflammatory disease." '504 patent. Hanmi challenges the validity of the '504 patent claims on written description and enablement grounds. Specifically, Hanmi alleges that the patent contains no written description showing that AstraZeneca was in possession of any hydrated form of esomeprazole salt, and, further, that there is no disclosure of how to make any such hydrated form. According to Hanmi, because AstraZeneca construes the asserted '504 patent claims to encompass Hanmi's proposed product, which contains esomeprazole strontium *tetrahydrate* as the active ingredient, the patent must meet the written description and enablement requirements of § 112 with respect hydrated forms of the alkaline salts of esomeprazole.

AstraZeneca argues in response to Hamni's motion that the '504 patent claims do not recite the term "hydrates" and, as such, the patent is not required to describe or enable such a form. First, AstraZeneca argues that Hamni is improperly importing a limitation into the patent's claim for the written description inquiry. Second, AstraZeneca contends that Hanmi's motion is improperly based upon a later-existing technology involving Hanmi's tetrahydrate

form. AstraZeneca's arguments rely primarily upon two cases*: Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, 1290-91 (D. Del. 1987), *aff'd* 865 F.2d 1247, 1290 (Fed. Cir. 1989) and *In re Hogan*, 559 F.2d 595, 605-07 (CCPA 1977).

In *Phillips*, the defendants argued that there was no written description support for the high molecular weight polypropylene used in its products. The claim at issue in that case read "Normally solid polypropylene, consisting essentially of recurring propylene units, having a substantial crystalline polypropylene content." 673 F. Supp. at 1286. The defendants specifically argued that the intrinsic viscosity for polypropylene disclosed in the application was less than the intrinsic viscosity of its own product. However, the Court rejected defendants' argument, noting that the claim at issue did not contain limitations regarding intrinsic viscosity or molecular weight:

> Defendants have misconstrued the inquiry under section 112. The focus of that inquiry is whether the claimed subject matter is adequately described. If the '851 claim contained a limitation regarding intrinsic viscosity or molecular weight, Defendants' arguments would have merit. Yet, the '851 claim contains no such limitation. The fact that the 1953 application specified a range of intrinsic iscosities of only 0.2 to 1.0 is, therefore, immaterial to the present inquiry.

Id. at 1291 (citations omitted). The *Phillips* court applied its analysis to both written description and enablement:

> Thus, with respect to both the written description and enablement requirements, Defendants have misconstrued the inquiry under section 112. They have sought to read into the '851 claim a molecular weight/intrinsic viscosity limitation which simply is not there. . . . A patent applicant is not required, however, to predict every possible variation, improvement or commercial embodiment of his invention. In seeking to impose such a requirement on Phillips, Defendants have wholly failed to carry their burden in establishing the insufficiency of Phillips' 1953 application under section 112.

Id at 1292 (citations omitted).

In *Hogan*, the patent application, filed in 1953, claimed a solid polymer, and the claims encompassed both crystalline and amorphous forms, even though the amorphous polymers did not exist until 1962. 559 F.2d at 605– 06. The specification disclosed methods for making the crystalline form, but not the amorphous polymers that it later became possible to produce. *Id.* The court stated that the patent application was not required to disclose the later-existing amorphous polymers:

> A later state of the art is that state coming into existence after the filing date of an application. This court has approved use of later publications as evidence of the state of art existing on the filing date of an application. That approval does not extend, however, to the use of a later . . . publication disclosing a later (1962) existing state of the art in testing an earlier (1953) application for compliance with s 112, first paragraph.
>
> . . .
>
> Appellants disclosed, as the only then existing way to make such a polymer, a method of making the crystalline form. To now say that appellants should have disclosed in 1953 the amorphous form which on this record did not exist until 1962, would be to impose an impossible burden on inventors and thus on the patent system. There cannot, in an effective patent system, be such a burden placed on the right to broad claims. To restrict appellants to the crystalline form disclosed, under such circumstances, would be a poor way to stimulate invention, and particularly to encourage its early disclosure. To demand such restriction is merely to state a policy against broad protection for pioneer inventions, a policy both shortsighted and unsound from the standpoint of promoting progress in the useful arts, the constitutional purpose of the patent laws.

Id. at 605–06 (citations omitted).

The Court finds that Hanmi has not established that it is entitled to summary judgment here. In light of *Phillips* and *Hogan*, Hanmi has not convinced the Court that "hydrates" are material to the written description or enablement inquiry, as such inquiries relate only to those matters set forth in the claims. Moreover, given the dueling expert reports submitted and the fact that the Court must draw all reasonable inferences in light of the non-moving party, the

Court finds that there exist factual issues that would preclude summary judgment in any event. As such, the Court denies Hanmi's motion.

III. CONCLUSION

For the reasons above, Hamni's Motion No. 2 (Invalidity Of U.S. Patent No. 5,877,192 – Claims 12, 19, 21, and 22), Motion No. 3 (Invalidity Of U.S. Patent No. 5,714,504 – Claims 1, 2, 4, 6, and 7), and Motion No. 4 (Invalidity Of U.S. Patent No. 5,714,504 – Claims 1, 2, 4, 6 and 7) are denied. An appropriate Order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: August 30, 2012